

I. Objections Under 35 U.S.C. § 132

The Examiner objects to the amendment to the specification indicating that R<sup>1</sup> may denote H. The Examiner asserts that this is new matter. Applicant has obviated the objection by amending the specification to remove the objected-to addition.

II. Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 1, 2, 4-20, 22-36, 49, 51-54, 56-57, 59-64 and 66-67 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter not described in the specification. The claims have been amended to remove hydrogen from the scope of R<sup>1</sup>. The claims have also been amended to remove the objected-to proviso.

Claims 1-36, 49, and 61-67 have been rejected under 35 U.S.C. §112, first paragraph, as non-enabled. The Examiner states that the scope of the R variables entails more than what is disclosed in the '828 patent, which is incorporated by reference in the pending application. The specification, however, merely cites the '828 patent as examples of compounds that are claimed. The specification provides ample guidance to one of ordinary skill in the art to prepare the family of compounds defined by the R groups. Whether certain R groups can make mirtazapine, which is just one compound in the family of claimed compounds, is not relevant to the pending claims. One of ordinary skill in the art would recognize that the R<sup>1</sup> groups, as defined in the amended claims, are suitable for the formation of the claimed compounds.

III. Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 1-36, 49, and 51-67 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner states that the scope of "aryl" requires clarification. Applicant respectfully disagrees. The term "aryl" is one used commonly in the art, and one of ordinary skill in the art would understand its scope. Applicant therefore respectfully requests that this rejection be withdrawn.

IV. Rejections Under 35 U.S.C. § 102(b)

Claims 49, 58-63 and 66 have been rejected under 35 U.S.C. §102(b) as being anticipated by Nickolson. Nickolson, however, does not disclose any compound within the scope of the claims as amended.

Claims 49, 63-64, and 66-67 have been rejected under 35 U.S.C. §102(b) as being anticipated by Lafon. Lafon, however, does not disclose any compound within the scope of the claims as amended.

Claims 1, 2, 4-10, 19-20, 22-28, 49, 58-61, 63 and 66-67 have been rejected under 35 U.S.C. §102(b) as being anticipated by Olivie '452. Olivie '452, however, does not disclose any compound within the scope of the claims as amended. Nor does Olivie '452 disclose a method of making the claimed compounds; Olivie '452 does not disclose, for example, structure V in claims 1 and 19.

V. Rejections Under 35 U.S.C. § 103(a)

Claims 1, 2, 4-10, 19-20, 22-28, 51-54, and 56-57 have been rejected under 35 U.S.C. §103(a) as obvious over Olivie ('513 or '452) and Van der Burg. For those reasons discussed above, neither Olivie nor Van der Burg, alone or in combination, discloses any compound within the scope of the compound claims as amended. In addition, Van der Burg does not disclose, for example, structure V in claims 1 and 19.

Claims 10-13 and 28-31 have been rejected under 35 U.S.C. §103(a) as obvious over Olivie ('513 or '452) and Van der Burg, and further in view of Winkley. Winkley, however, does not overcome the deficiencies of Olivie and Van der Burg.

VI. Rejections For Obviousness-Type Double Patenting

Claims 1-36, 49, 51-53, 55-63 and 65-67 have been rejected for obviousness-type double patenting over the claims of U.S. Patent No. 6,339,156. Should the examiner maintain the rejections of the claims, as currently amended, Applicants will address the rejections, such as by filing a terminal disclaimer.

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**CONCLUSION**

In view of the foregoing amendments and remarks, an early and favorable action on the merits is earnestly solicited. The Examiner is invited to contact the undersigned attorney if such communication is believed to be helpful in advancing the examination of the present application. The Office is hereby authorized to charge any additional fees or credit any overpayments under 37 C.F.R. §1.16 or §1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

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**MARKED-UP VERSION SHOWING CHANGES**

**IN THE SPECIFICATION**

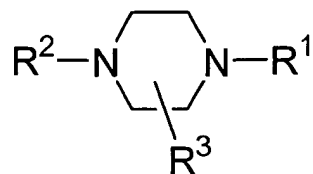
Page 1, paragraph 1:

Delete the indicated paragraph and replace it with the following:

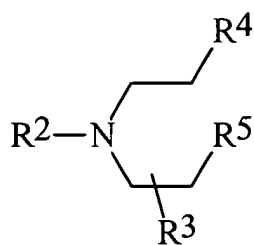
This application is a continuation of application serial number 09/545,011, filed April 7, 2000, now U.S. Patent No. 6,339,156, which claims the benefit under 35 U.S.C. § 119(e) of U.S. Provisional Application Serial No. 60/130,048, filed April 19, 1999.

Page 2, paragraph 1:

The present invention relates to a novel process for preparing a compound of the formula I:



wherein R<sup>1</sup> denotes substituted or unsubstituted [hydrogen,] alkyl, aryl, arylalkoxy, tosyl, formyl, benzoyl, acetyl or amine; R<sup>2</sup> denotes substituted or unsubstituted alkyl, alkoxy, aryl, aryloxy or arylalkoxy; and R<sup>3</sup> denotes substituted or unsubstituted alkyl, alkoxy, aryl, aryloxy or arylalkoxy; by reacting a compound of the formula



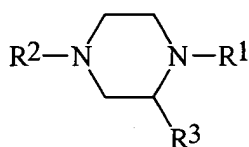
II

wherein  $R^2$  and  $R^3$  are as defined above and  $R^4$  and  $R^5$  are independently selected from the group consisting of fluoro, chloro, bromo and iodo,

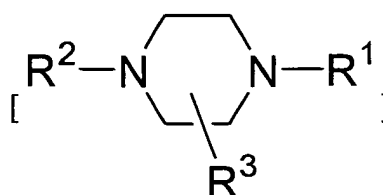
with a compound of the formula  $H_2N-R^1$ , wherein  $R^1$  is as defined above. Preferably the reaction is performed in the presence of a solvent. Polar aprotic solvents such as, dimethyl formamide, dimethylacetamide and dimethylsulfoxide are preferred.

### IN THE CLAIMS

- (Amended) A method for preparing a compound of the formula



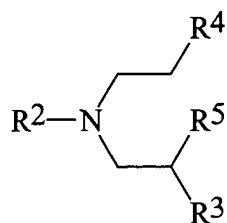
IV



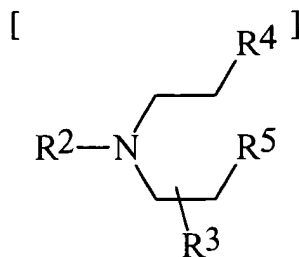
wherein  $R^1$  denotes [H,] alkyl, [aryl, arylalkoxy] phenyl, phenylalkoxy, tosyl, benzoyl, or formyl, [acetyl or amino, with the proviso that  $R^1$  does not denote  $-Ph-CH_2-X$ , where X is hydroxy or a halogen];  $R^2$  denotes alkyl, alkoxy, [aryl, aryloxy or arylalkoxy] phenyl, phenyloxy or

phenylalkoxy; and  $R^3$  denotes alkyl, alkoxy, [aryl, aryloxy or arylalkoxy] phenyl, phenyloxy or phenylalkoxy,

comprising the step of reacting a compound of the formula



V

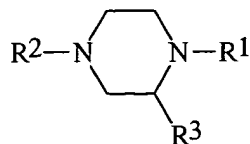


II

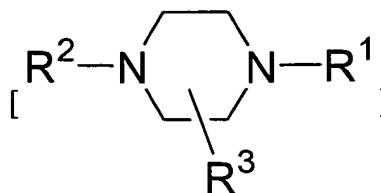
wherein  $R^2$  and  $R^3$  are as defined above and  $R^4$  and  $R^5$  are independently selected from the group consisting of fluoro, chloro, bromo and iodo,

with a compound of the formula  $H_2N-R^1$ , wherein  $R^1$  is as defined above.

49. (Amended) A compound of the formula:



IV



wherein  $R^1$  denotes [H,] alkyl, [aryl, arylalkoxy,] tosyl, formyl, or benzoyl, [acetyl or amino, with the proviso that  $R^1$  does not denote  $-Ph-CH_2-X$ , where X is hydroxy or a halogen];  $R^2$  denotes alkyl, alkoxy, [aryl, aryloxy or arylalkoxy] phenyl, phenyloxy or phenylalkoxy; and  $R^3$  denotes alkyl, alkoxy, aryl, aryloxy or arylalkoxy.

53. (Amended) The method of claim 1, wherein R<sup>1</sup> denotes [H, alkyl, aryl, arylalkoxy,] tosyl, [formyl, benzoyl, acetyl or amino]; R<sup>2</sup> is alkyl, phenyl, phenyloxy or phenylalkoxy; and R<sup>3</sup> is [aryl] phenyl or alkyl.
54. (Amended) The method of claim 1, wherein R<sup>1</sup> denotes [H] alkyl, tosyl, formyl, or benzoyl; R<sup>2</sup> is alkyl; and R<sup>3</sup> is [aryl] phenyl.
58. (Amended) The compound of claim 49, wherein R<sup>1</sup> is [selected from the group consisting of] alkyl, [aryl, acetyl,] formyl, benzoyl, or [amine and] tosyl; and R<sup>3</sup> is alkyl, alkoxo, phenyl, phenyloxy or phenylalkoxy.
63. (Amended) The compound of claim [49] 58, wherein R<sup>1</sup> denotes [H, alkyl, aryl, arylalkoxy,] tosyl[, formyl, benzoyl, acetyl or amino]; R<sup>2</sup> is alkyl; and R<sup>3</sup> is [aryl] phenyl.